

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION,
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

GARY BREWER, et al.,
Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE LLC, (FKA G.D. SEARLE &
CO.),

Defendants.

) MDL Docket No. 1699
)
) CASE NO. 3:07-cv-4031-CRB
)
) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**
)
) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 ("Searle"), (collectively "Defendants") and file this Answer to Plaintiffs' Complaint
4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used
8 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
9 generally. Defendants may seek leave to amend this Answer when discovery reveals the
10 specific time periods in which Plaintiffs were prescribed and used Celebrex®.

11 **II.**

12 **ANSWER**

13 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,
14 Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny
15 that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain
16 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United
17 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
18 accordance with their approval by the FDA. Defendants admit that, during certain periods of
19 time, Celebrex® was manufactured and packaged for Searle, which developed, tested,
20 marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by
21 healthcare providers who are by law authorized to prescribe drugs in accordance with their
22 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
23 in accordance with its FDA-approved prescribing information. Defendants state that the
24 potential effects of Celebrex® were and are adequately described in its FDA-approved
25 prescribing information, which was at all times adequate and comported with applicable
26 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused
27 Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the
28

1 Complaint.

2 **Response to Allegations Regarding Parties**

3 1. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' age, and
5 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 2. Defendants admit that Pfizer is a Delaware corporation with its principal place of
8 business in New York. Defendants admit that, as the result of a merger in April 2003,
9 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph
10 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants
11 are without knowledge or information sufficient to form a belief as to the truth of such
12 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of
13 time, Pfizer marketed and co-promoted Celebrex® in the United States, including California,
14 New York, Florida, Missouri, Washington, Alabama, and Michigan, to be prescribed by
15 healthcare providers who are by law authorized to prescribe drugs in accordance with their
16 approval by the FDA. Defendants deny the remaining allegations in this paragraph of the
17 Complaint.

18 3. Defendants admit that Searle is a Delaware limited liability company with its principal
19 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,
20 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
21 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
22 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
23 Celebrex® in the United States to be prescribed by healthcare providers who are by law
24 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
25 the remaining allegations in this paragraph of the Complaint.

26 4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
27 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
28

1 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
2 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted
3 Celebrex® in the United States, including California, New York, Florida, Missouri,
4 Washington, Alabama, and Michigan,, to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
6 the remaining allegations in this paragraph of the Complaint.

7 5. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
9 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
10 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
11 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
14 that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle
15 and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this
16 paragraph of the Complaint.

17 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
18 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
19 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
20 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
21 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
22 Celebrex® in the United States to be prescribed by healthcare providers who are by law
23 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
24 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
25 prescribing information. Defendants state that the potential effects of Celebrex® were and are
26 adequately described in its FDA-approved prescribing information, which was at all times
27 adequate and comported with applicable standards of care and law. Defendants deny any
28

1 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

2 7. Defendants state that the allegations in this paragraph of the Complaint regarding
3 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
4 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
5 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

6 **Response to Allegations Regarding Jurisdiction and Venue**

7 8. Defendants are without knowledge or information to form a belief as to the truth of the
8 allegations in this paragraph of the Complaint regarding Plaintiffs’ citizenship and the amount
9 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim
10 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of
11 interests and costs.

12 9. Defendants are without knowledge or information to form a belief as to the truth of the
13 allegations in this paragraph of the Complaint regarding the judicial district in which the
14 asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex®
15 was and is safe and effective when used in accordance with its FDA-approved prescribing
16 information. Defendants deny committing a tort in the States of California, New York, Florida,
17 Missouri, Washington, Alabama, and Michigan, and deny the remaining allegations in this
18 paragraph of the Complaint.

19 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
20 and co-promoted Celebrex® in the United States, including California, New York, Florida,
21 Missouri, Washington, Alabama, and Michigan, to be prescribed by healthcare providers who
22 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
23 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
24 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
25 Celebrex® in the United States to be prescribed by healthcare providers who are by law
26 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
27 that Pfizer, Pharmacia, and Searle are registered to and do business in the States of California,
28

1 New York, Florida, Missouri, Washington, Alabama, and Michigan. Defendants state that the
2 allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague
3 and ambiguous. Defendants are without knowledge or information sufficient to form a belief as
4 to the truth of such allegations, and, therefore, deny the same. Defendants deny committing a
5 tort in the States of California, New York, Florida, Missouri, Washington, Alabama, and
6 Michigan, and deny the remaining allegations in this paragraph of the Complaint.

7
8 **Response to Allegations Regarding Interdistrict Assignment**

9 11. Defendants state that this paragraph of the Complaint contains legal contentions to
10 which no response is required. To the extent that a response is deemed required, Defendants
11 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
12 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
13 Panel on Multidistrict Litigation on September 6, 2005.

14 **Response to Factual Allegations**

15 12. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s age, citizenship,
17 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
18 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
19 FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
23 and deny the remaining allegations in this paragraph of the Complaint.

24 13. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s age, citizenship,
26 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
27 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
28 FDA-approved prescribing information. Defendants state that the potential effects of

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
4 and deny the remaining allegations in this paragraph of the Complaint.

5 14. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
7 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
8 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
13 and deny the remaining allegations in this paragraph of the Complaint.

14 15. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
16 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
17 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
18 FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
22 and deny the remaining allegations in this paragraph of the Complaint.

23 16. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
25 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
26 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
27 FDA-approved prescribing information. Defendants state that the potential effects of
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
4 and deny the remaining allegations in this paragraph of the Complaint.

5 17. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
7 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
8 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
13 and deny the remaining allegations in this paragraph of the Complaint.

14 18. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
16 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
17 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
18 FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
22 and deny the remaining allegations in this paragraph of the Complaint.

23 19. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
25 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
26 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
27 FDA-approved prescribing information. Defendants state that the potential effects of
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
4 and deny the remaining allegations in this paragraph of the Complaint.

5 20. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
7 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
8 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
13 and deny the remaining allegations in this paragraph of the Complaint.

14 21. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
16 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
17 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
18 FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
22 and deny the remaining allegations in this paragraph of the Complaint.

23 22. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
25 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
26 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
27 FDA-approved prescribing information. Defendants state that the potential effects of
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
4 and deny the remaining allegations in this paragraph of the Complaint.

5 23. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiffs injury
12 or damage and deny the remaining allegations in this paragraph of the Complaint.

13 24. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
15 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
20 Celebrex® caused Plaintiffs injury or damage and deny the remaining allegations in this
21 paragraph of the Complaint.

22 25. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
24 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
25 Celebrex® was expected to reach users and consumers without substantial change from the
26 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 26. Defendants are without knowledge or information sufficient to form a belief as to the
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
2 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-
5 approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
7 remaining allegations in this paragraph of the Complaint.

8 27. Defendants state that Plaintiffs fail to provide the proper context for the allegations in
9 this paragraph of the Complaint regarding “Decedents.” Defendants are without knowledge or
10 information sufficient to form a belief as to the truth of the allegations in this paragraph of the
11 Complaint regarding such allegations. and, therefore, deny the same. Defendants state that
12 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
13 prescribing information. Defendants state that the potential effects of Celebrex® were and are
14 adequately described in its FDA-approved prescribing information, which was at all times
15 adequate and comported with applicable standards of care and law. Defendants deny any
16 wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the
17 remaining allegations in this paragraph of the Complaint, including all subparts.

18 28. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 29. Defendants state that the allegations in this paragraph of the Complaint regarding
21 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no
22 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,
23 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the
24 remaining allegations in this paragraph of the Complaint.

25 30. Defendants state that the allegations in this paragraph of the Complaint are not directed
26 towards Defendants and, therefore, no response is required. To the extent that a response is
27 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
2 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

3 31. Defendants state that the allegations in this paragraph of the Complaint are not directed
4 towards Defendants and, therefore, no response is required. To the extent that a response is
5 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
6 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
7 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

8 32. Defendants state that the allegations in this paragraph of the Complaint are not directed
9 towards Defendants and, therefore, no response is required. To the extent that a response is
10 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
11 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
12 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

13 33. Defendants state that the allegations in this paragraph of the Complaint regarding “other
14 pharmaceutical companies” are not directed towards Defendants and, therefore, no response is
15 required. To the extent a response is deemed required, Defendants state that, as stated in the
16 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to
17 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2
18 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the
19 cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiffs fail to provide the proper context for the
20 remaining allegations in this paragraph and Defendants therefore lack sufficient information or
21 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining
22 allegations in this paragraph of the Complaint.

23 34. Defendants state that the allegations in this paragraph of the Complaint regarding
24 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
25 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
26 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
27 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
2 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants
3 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
4 approved prescribing information. Defendants state that the potential effects of Celebrex®
5 were and are adequately described in its FDA-approved prescribing information, which was at
6 all times adequate and comported with applicable standards of care and law. Defendants deny
7 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

8 35. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
9 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
10 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of
11 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
12 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
13 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis
14 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny
15 the remaining allegations in this paragraph of the Complaint.

16 36. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
17 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
20 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
21 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
22 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
23 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
24 and effective when used in accordance with its FDA-approved prescribing information.
25 Defendants state that the potential effects of Celebrex® were and are adequately described in its
26 FDA-approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28

1 remaining allegations in this paragraph of the Complaint.

2 37. Defendants state that the referenced article speaks for itself and respectfully refer the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
6 this paragraph of the Complaint.

7 38. Defendants state that the referenced article speaks for itself and respectfully refer the
8 Court to the article for its actual language and text. Any attempt to characterize the article is
9 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
11 this paragraph of the Complaint.

12 39. Defendants state that the referenced FDA Update speaks for itself and respectfully refer
13 the Court to the FDA Update for its actual language and text. Any attempt to characterize the
14 FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when
15 used in accordance with its FDA-approved prescribing information. Defendants state that the
16 potential effects of Celebrex® were and are adequately described in its FDA-approved
17 prescribing information, which was at all times adequate and comported with applicable
18 standards of care and law. Defendants deny the remaining allegations in this paragraph of the
19 Complaint.

20 40. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 41. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 42. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA
5 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
6 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
7 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself
8 and respectfully refer the Court to the study for its actual language and text. Any attempt to
9 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
10 the Complaint.

11 43. Defendants state that the referenced article speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 44. Defendants state that the referenced study speaks for itself and respectfully refer the
15 Court to the study for its actual language and text. Any attempt to characterize the study is
16 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
17 paragraph of the Complaint.

18 45. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee
19 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual
20 language and text. Any attempt to characterize the transcripts is denied. Defendants deny any
21 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

22 46. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee
23 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual
24 language and text. Any attempt to characterize the transcripts is denied. Defendants deny any
25 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

26 47. Defendants state that the referenced articles speak for themselves and respectfully refer
27 the Court to the articles for their actual language and text. Any attempt to characterize the
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
2 refer the Court to the study for its actual language and text. Any attempt to characterize the
3 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 48. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
7 paragraph of the Complaint.

8 49. Defendants state that the referenced articles speak for themselves and respectfully refer
9 the Court to the articles for their actual language and text. Any attempt to characterize the
10 articles is denied. Defendants deny the remaining allegations in this paragraph of the
11 Complaint.

12 50. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
15 Court to the study for its actual language and text. Any attempt to characterize the study is
16 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 51. Defendants state that the referenced Medical Officer Review speaks for itself and
18 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
19 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
20 allegations in this paragraph of the Complaint.

21 52. Plaintiffs fail to provide the proper context for the allegations concerning "Public
22 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or
23 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 53. Defendants state that the referenced article speaks for itself and respectfully refer the
26 Court to the article for its actual language and text. Any attempt to characterize the article is
27 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
28

1 paragraph of the Complaint.

2 54. Defendants state that the referenced study speaks for itself and respectfully refer the
3 Court to the study for its actual language and text. Any attempt to characterize the study is
4 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public
5 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
6 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 55. Defendants admit that there was a clinical trial called APC. Defendants state that the
9 referenced article speaks for itself and respectfully refer the Court to the article for its actual
10 language and text. Any attempt to characterize the article is denied. Defendants deny the
11 remaining allegations in this paragraph of the Complaint.

12 56. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Data Safety
15 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
16 information or knowledge to form a belief as to the truth of such allegations and, therefore,
17 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

18 57. Defendants state that the referenced article speaks for itself and respectfully refer the
19 Court to the article for its actual language and text. Any attempt to characterize the article is
20 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 58. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
22 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
23 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 59. Defendants state that the referenced Medical Officer Review speaks for itself and
26 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
27 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 allegations in this paragraph of the Complaint.

2 60. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide
3 the proper context for the allegations concerning “other Celebrex trials” contained in this
4 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
5 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
6 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
7 that the referenced study speaks for itself and respectfully refer the Court to the study for its
8 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
9 remaining allegations in this paragraph of the Complaint.

10 61. Defendants state that the referenced article speaks for itself and respectfully refer the
11 Court to the article for its actual language and text. Any attempt to characterize the article is
12 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 62. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the
14 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
15 therefore lack sufficient information or knowledge to form a belief as to the truth of such
16 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for
17 themselves and respectfully refer the Court to the studies for their actual language and text.
18 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
19 this paragraph of the Complaint.

20 63. Defendants state that the referenced Medical Officer Review speaks for itself and
21 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
22 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
23 allegations in this paragraph of the Complaint.

24 64. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint
25 are not directed toward Defendants, and therefore no response is required. To the extent that a
26 response is deemed required, Plaintiffs fail to provide the proper context for the allegations in
27 this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
2 such allegations and, therefore, deny the same. Defendants state that the referenced study
3 speaks for itself and respectfully refer the Court to the study for its actual language and text.
4 Any attempt to characterize the study is denied. Defendants deny the remaining allegations in
5 this paragraph of the Complaint.

6 65. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
7 Complaint are not directed toward Defendants, and therefore no response is required. To the
8 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the
9 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
10 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
11 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
12 referenced study speaks for itself and respectfully refer the Court to the study for its actual
13 language and text. Any attempt to characterize the study is denied. Defendants deny the
14 remaining allegations in this paragraph of the Complaint.

15 66. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
16 Complaint are not directed toward Defendants, and therefore no response is required. To the
17 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the
18 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
19 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
20 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
21 referenced study speaks for itself and respectfully refer the Court to the study for its actual
22 language and text. Any attempt to characterize the study is denied. Defendants state that the
23 referenced article speaks for itself and respectfully refer the Court to the article for its actual
24 language and text. Any attempt to characterize the article is denied. Defendants deny the
25 remaining allegations in this paragraph of the Complaint.

26 67. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants deny the allegations in this
28

1 paragraph of the Complaint.

2 68. Defendants state that the referenced article speaks for itself and respectfully refer the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 69. Defendants state that allegations in this paragraph of the Complaint are not directed
6 toward Defendants, and therefore no response is required. To the extent that a response is
7 deemed required, Defendants state that the referenced article speaks for itself and respectfully
8 refer the Court to the article for its actual language and text. Any attempt to characterize the
9 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 70. Defendants deny the allegations in this paragraph of the Complaint.

11 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
16 remaining allegations contained in this paragraph of the Complaint.

17 72. Defendants deny any wrongful conduct and deny the allegations contained in this
18 paragraph of the Complaint.

19 73. Defendants deny any wrongful conduct and deny the allegations contained in this
20 paragraph of the Complaint.

21 74. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
26 paragraph of the Complaint.

27 75. Defendants are without knowledge or information sufficient to form a belief as to the
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
2 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-
5 approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
7 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of
8 the Complaint.

9 76. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
10 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and
11 November 14, 2000. Defendants state that the referenced letters speak for themselves and
12 respectfully refer the Court to the letters for their actual language and text. Any attempt to
13 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph
14 of the Complaint.

15 77. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.
16 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
17 the letter for its actual language and text. Any attempt to characterize the letter is denied.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 78. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 79. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.
23 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
24 the letter for its actual language and text. Any attempt to characterize the letter is denied.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
4 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
5 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
6 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
7 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
8 United States to be prescribed by healthcare providers who are by law authorized to prescribe
9 drugs in accordance with their approval by the FDA. Defendants deny the remaining
10 allegations in this paragraph of the Complaint.

11 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
16 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
17 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
18 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
19 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
20 United States to be prescribed by healthcare providers who are by law authorized to prescribe
21 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a
22 prescription medication which is approved by the FDA for the following indications: (1) for
23 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
24 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
25 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
26 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
27 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
2 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this
3 paragraph of the Complaint.

4 82. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which at all times was adequate and comported with applicable standards of care and law.
8 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and
9 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
10 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
11 that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

12 83. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
17 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
18 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
19 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
20 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
21 United States to be prescribed by healthcare providers who are by law authorized to prescribe
22 drugs in accordance with their approval by the FDA. Defendants deny the remaining
23 allegations in this paragraph of the Complaint.

24 84. Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which at all times was adequate and comported with applicable standards of care and law.
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
2 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
3 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
4 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
5 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
6 United States to be prescribed by healthcare providers who are by law authorized to prescribe
7 drugs in accordance with their approval by the FDA. Defendants deny the remaining
8 allegations in this paragraph of the Complaint.

9 85. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
14 the Complaint.

15 86. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
20 the Complaint.

21 87. Defendants deny the allegations in this paragraph of the Complaint.

22 88. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 89. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 90. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
9 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
10 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
11 paragraph of the Complaint.

12 91. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
17 remaining allegations in this paragraph of the Complaint.

18 92. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® are and were adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 93. Defendants deny any wrongful conduct and deny the remaining allegations in this
25 paragraph of the Complaint.

26 94. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
28

1 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® are and were adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7
8 **Response to First Cause of Action: Negligence**

9 95. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
10 Complaint as if fully set forth herein.

11 96. Defendants state that this paragraph of the Complaint contains legal contentions to
12 which no response is required. To the extent that a response is deemed required, Defendants
13 admit that they had duties as are imposed by law but deny having breached such duties.
14 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
15 FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 97. Defendants state that this paragraph of the Complaint contains legal contentions to
21 which no response is required. To the extent that a response is deemed required, Defendants
22 admit that they had duties as are imposed by law but deny having breached such duties.
23 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
24 FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 98. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
3 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations in this paragraph of the Complaint, including all subparts.

9 99. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 100. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 101. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
25 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-
28

1 approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
3 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
4 paragraph of the Complaint.

5 102. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' medical
7 conditions and whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants
8 deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny
9 the remaining allegations in this paragraph of the Complaint.

10 103. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
11 damage, and deny the remaining allegations in this paragraph of the Complaint.

12 104. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 **Response to Second Cause of Action: Strict Liability**

15 105. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
16 Complaint as if fully set forth herein.

17 106. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
19 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
20 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
21 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
22 with their approval by the FDA. Defendants admit that, during certain periods of time,
23 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
24 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
25 providers who are by law authorized to prescribe drugs in accordance with their approval by the
26 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
27 consumers without substantial change from the time of sale. Defendants deny the remaining
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 allegations in this paragraph of the Complaint.

2 107. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny the remaining allegations in this paragraph of the Complaint.

7 108. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
12 remaining allegations in this paragraph of the Complaint.

13 109. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
18 remaining allegations in this paragraph of the Complaint, including all subparts.

19 110. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
26 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the
27 remaining allegations in this paragraph of the Complaint.
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 111. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
6 remaining allegations in this paragraph of the Complaint.

7 112. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
14 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the
15 remaining allegations in this paragraph of the Complaint.

16 113. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 114. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
2 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this
3 paragraph of the Complaint.

4 115. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 116. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
17 remaining allegations in this paragraph of the Complaint.

18 117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 118. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Third Cause of Action: Breach of Express Warranty**

25 120. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
26 Complaint as if fully set forth herein.

27 121. Defendants are without knowledge or information sufficient to form a belief as to the
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
2 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-
5 approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants admit that they provided FDA-approved
7 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
8 this paragraph of the Complaint.

9 122. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants admit that they provided FDA-approved
16 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and
17 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

18 123. Defendants admit that they provided FDA-approved prescribing information regarding
19 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this
20 paragraph of the Complaint.

21 124. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 125. Defendants state that Celebrex® was and is safe and effective when used in accordance
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 126. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
8 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants admit that they provided FDA-approved prescribing information regarding
12 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 127. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
16 damage, and deny the remaining allegations in this paragraph of the Complaint.

17 129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
18 damage, and deny the remaining allegations in this paragraph of the Complaint.

19 **Response to Fourth Cause of Action: Breach of Implied Warranty**

20 130. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
21 Complaint as if fully set forth herein.

22 131. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
23 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
24 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
25 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
26 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
27 Celebrex® in the United States to be prescribed by healthcare providers who are by law
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
2 the remaining allegations in this paragraph of the Complaint.

3 132. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants admit that they provided FDA-approved prescribing information regarding
8 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 133. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 134. Defendants state that this paragraph of the Complaint contains legal contentions to
15 which no response is required. To the extent that a response is deemed required, Defendants
16 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
17 approved prescribing information. Defendants state that the potential effects of Celebrex®
18 were and are adequately described in its FDA-approved prescribing information, which was at
19 all times adequate and comported with applicable standards of care and law. Defendants deny
20 any wrongful conduct, deny that they breached any warranty, and deny the remaining
21 allegations in this paragraph of the Complaint.

22 135. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
25 medication which is approved by the FDA for the following indications: (1) for relief of the
26 signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid
27 arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
2 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
3 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the
4 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 136. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
8 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Celebrex® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants admit that they provided FDA-approved
13 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
14 this paragraph of the Complaint.

15 137. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
17 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
18 Celebrex® was expected to reach users and consumers without substantial change from the
19 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 138. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
22 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they
27 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.
28

1 139. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 140. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 141. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

8 142. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
9 Complaint as if fully set forth herein.

10 143. Defendants state that this paragraph of the Complaint contains legal contentions to
11 which no response is required. To the extent that a response is deemed required, Defendants
12 admit that they had duties as are imposed by law but deny having breached such duties.
13 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
14 FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 144. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint, including all subparts.

25 145. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 146. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
6 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
11 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this
12 paragraph of the Complaint.

13 147. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 148. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 149. Defendants are without knowledge or information sufficient to form a belief as to the
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
2 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-
5 approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
7 remaining allegations in this paragraph of the Complaint.

8 150. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
10 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
15 remaining allegations in this paragraph of the Complaint.

16 151. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
18 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
23 remaining allegations in this paragraph of the Complaint.

24 152. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
26 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 153. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 154. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 155. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
16 damage, and deny the remaining allegations in this paragraph of the Complaint.

17 156. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
18 damage, and deny the remaining allegations in this paragraph of the Complaint.

19 **Response to Sixth Cause of Action: Unjust Enrichment**

20 157. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
21 Complaint as if fully set forth herein.

22 158. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
23 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
24 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
25 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
26 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
27 Celebrex® in the United States to be prescribed by healthcare providers who are by law
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
2 the remaining allegations in this paragraph of the Complaint.

3 159. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
5 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 160. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
9 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
10 paragraph of the Complaint.

11 161. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
13 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 162. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 163. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
28

1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 **Response to Seventh Cause of Action:**

3 **State Consumer Fraud and Deceptive Trade Practices Act**

4 164. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
5 Complaint as if fully set forth herein.

6 165. Defendants state that this paragraph of the Complaint contains legal contentions to
7 which no response is required. To the extent that a response is deemed required, Defendants
8 admit that they had duties as are imposed by law but deny having breached such duties.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 166. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding whether Plaintiffs used Celebrex® and, therefore, deny the
12 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 167. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations regarding whether Plaintiffs used Celebrex® and, therefore, deny the
20 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 168. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations regarding whether Plaintiffs used Celebrex® and, therefore, deny the
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 169. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations regarding whether Plaintiffs used Celebrex® and, therefore, deny the
4 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 170. Defendants state that this paragraph of the Complaint contains legal contentions to
11 which no response is required. To the extent that a response is deemed required, Defendants
12 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
13 Complaint.

14 171. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 172. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 173. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 174. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 175. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Prayer For Relief**

25 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
26 damage, and deny the remaining allegations in paragraph of the Complaint headed "Prayer for
27 Relief," including all subparts.
28

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the

1 prescribing physician and the medical profession, which act as a “learned intermediary” in
2 determining the use of the product. Celebrex® is a prescription medical product, available only
3 on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’
4 treating and prescribing physicians.

5 **Thirteenth Defense**

6 13. The product at issue was not in a defective condition or unreasonably dangerous at the
7 time it left the control of the manufacturer or seller.

8 **Fourteenth Defense**

9 14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit
10 for its intended use and the warnings and instructions accompanying Celebrex® at the time of
11 the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved
12 usages.

13 **Fifteenth Defense**

14 15. Plaintiffs’ causes of action are barred in whole or in part by the lack of a defect as the
15 Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable
16 standard of care.

17 **Sixteenth Defense**

18 16. Plaintiffs’ alleged injuries/damages, if any, were the result of misuse or abnormal use of
19 the product Celebrex® after the product left the control of Defendants and any liability of
20 Defendants is therefore barred.

21 **Seventeenth Defense**

22 17. Plaintiffs’ alleged damages were not caused by any failure to warn on the part of
23 Defendants.

24 **Eighteenth Defense**

25 18. Plaintiffs’ alleged injuries/damages, if any, were the result of preexisting or subsequent
26 conditions unrelated to Celebrex®.

27
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of California, New York, Florida, Missouri, Washington, Alabama, and Michigan, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of California, New York, Florida, Missouri, Washington, Alabama, and Michigan. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to
2 guide and restrain the jury's discretion in determining whether to award punitive damages
3 and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance
4 notice as to what conduct will result in punitive damages; (3) permits recovery of punitive
5 damages based on out-of-state conduct, conduct that complied with applicable law, or conduct
6 that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of
7 punitive damages in an amount that is not both reasonable and proportionate to the amount of
8 harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury
9 consideration of net worth or other financial information relating to Defendants; (6) lacks
10 constitutionally sufficient standards to be applied by the trial court in post-verdict review of any
11 punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of
12 punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including,
13 without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO*
14 *Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America,*
15 *Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S.
16 408 (2003).

Thirty-ninth Defense

18 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
19 and marketing of Celebrex®, if any, used in this case, included adequate warnings and
20 instructions with respect to the product's use in the package insert and other literature, and
21 conformed to the generally recognized, reasonably available, and reliable state of the
22 knowledge at the time the product was marketed.

Fortieth Defense

24 40. The claims asserted in the Complaint are barred because Celebrex® was designed,
25 tested, manufactured and labeled in accordance with the state-of-the-art industry standards
26 existing at the time of the sale.
27
28

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by

1 any applicable regulatory body, including but not limited to the United States, any state, and
2 any agency thereof.

3 **Forty-eighth Defense**

4 48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if
5 the product labeling contained the information that Plaintiffs contend should have been
6 provided.

7 **Forty-ninth Defense**

8 49. The claims asserted in the Complaint are barred because the utility of Celebrex®
9 outweighed its risks.

10 **Fiftieth Defense**

11 50. Plaintiffs' damages, if any, are barred or limited by the payments received from
12 collateral sources.

13 **Fifty-first Defense**

14 51. Defendants' liability, if any, can only be determined after the percentages of
15 responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if
16 any, are determined. Defendants seek an adjudication of the percentage of fault of the
17 claimants and each and every other person whose fault could have contributed to the alleged
18 injuries and damages, if any, of Plaintiffs.

19 **Fifty-second Defense**

20 52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the
21 common law gives deference to discretionary actions by the United States Food and Drug
22 Administration under the Federal Food, Drug, and Cosmetic Act.

23 **Fifty-third Defense**

24 53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
25 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
26 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs'
27 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
28

1 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
2 and with the specific determinations by FDA specifying the language that should be used in the
3 labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the
4 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
5 United States.

6 **Fifty-fourth Defense**

7 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity
8 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

9 **Fifty-fifth Defense**

10 55. Defendants state on information and belief that the Complaint and each purported cause
11 of action contained therein is barred by the statutes of limitations contained in California Code
12 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation
13 as may apply.

14 **Fifty-sixth Defense**

15 56. Defendants state on information and belief that any injuries, losses, or damages suffered
16 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable
17 conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against
18 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

19 **Fifty-seventh Defense**

20 57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of
21 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
22 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
23 damages is also barred under California Civil Code § 3294(b).

24 **Fifty-eighth Defense**

25 58. The products in question were approved as safe and effective by the FDA and the
26 labeling for said products were in compliance with FDA's approval at the time the products left
27 the control of one or more Defendants and hence, Plaintiffs' claims are barred by MCL
28

1 600.2946(5).

2 **Fifty-ninth Defense**

3 59. Plaintiffs' claim for non-economic damages is capped pursuant to MCL 600.2946a.

4 **Sixtieth Defense**

5 60. To the extent Plaintiffs prove that the products in question caused or contributed to any
6 injury Plaintiffs may have suffered, which is denied by these Defendants, these Defendants
7 should not be liable to warn as Plaintiffs cannot prove that the scientific, technical or medical
8 information that was reasonably available at the time was known or should have been known by
9 the Defendants. MCL 600.2948.

10 **Sixty-first Defense**

11 61. Defendants assert all of the protections and defenses afforded them, and Plaintiffs'
12 claims of liability or damages are limited pursuant to the Michigan Products Liability Act
13 including specifically, but not limited to MCL 600.2946 through MCL 600.6306, including
14 MCL 600.2946, MCL 600.2946(a), MCL 600.2947, MCL 600.2948, MCL 600.2956, MCL
15 600.2957 and MCL 600.2959.

16 **Sixty-second Defense**

17 62. The products alleged to have caused damages may not have been used in the manner
18 and for the purposes intended. Such improper use and/or abuse of the products for an
19 unforeseeable purpose and in an unforeseeable manner may have proximately caused or
20 contributed to the alleged injuries, if any, and therefore there is no recovery available against
21 Defendants pursuant to MCL 600.2947.

22 **Sixty-third Defense**

23 63. Plaintiffs' claim for non-economic damages is barred for the reason that Plaintiffs'
24 percentage of comparative fault is greater than the aggregate fault of the Defendants and non-
25 parties hereto, pursuant to MCL 600.2959 and MCL 600.6306; but that to the extent allowable,
26 must be reduced in total or part pursuant to 600.2946(a).

Sixty-fourth Defense

64. The claims set forth in Plaintiffs' Complaint are barred in that the products in question were provided to a sophisticated user. In this case, the "user" would include any prescribing physician.

Sixty-fifth Defense

65. Plaintiffs failed to make every reasonable effort to mitigate, prevent and/or reduce their alleged damages, injuries, and monetary losses.

Sixty-sixth Defense

66. Plaintiffs' claims, part of Plaintiffs' claims, or evidence relating to Plaintiffs' claims may be barred in whole or in part due to possible spoliation of evidence by Plaintiffs, or those within Plaintiffs' control or with full knowledge of Plaintiffs.

Sixty-seventh Defense

67. Any claims for punitive damages are barred in that they are not allowable under Michigan law. To the extent that they are allowed contrary to Michigan law, such claims further violate Defendants' constitutional rights under the following clauses of the United States Constitution, as well as any similar provisions under the Michigan Constitution: Commerce Clause, Contracts Clause, Supremacy Clause, Due Process, Takings Clause, Excessive Fines and Equal Protection.

Sixty-eighth Defense

68. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by Rule 1.120 of the Florida Rules of Civil Procedure.

Sixty-ninth Defense

69. Plaintiffs' claims are barred because Celebrex® was designed, manufactured, and marketed in accordance with the state of the art at the time of manufacture per § 768.1257, Florida Statutes.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Seventieth Defense

70. Celebrex® is not defective or unreasonably dangerous, and Defendants are not liable because, at the time of sale or distribution of the Celebrex® alleged to have been used by Plaintiffs, Defendants had complied with applicable regulations of the federal Food & Drug Administration and are entitled to application of § 768.1256, Florida Statutes.

Seventy-first Defense

71. Plaintiffs' injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiffs, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs' recovery. Thus, Defendants are entitled to have their liability to the Plaintiffs, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of § 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to §§ 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262 (Fla. 1996).

Seventy-second Defense

72. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

Seventy-third Defense

73. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs' FDUTPA claim is improper and should be dismissed.

Seventy-fourth Defense

74. The acts or practices of which Plaintiffs complain were and are required or specifically permitted by federal or state law. Therefore, Plaintiffs' FDUTPA claim is barred, fails to state a claim, and should be dismissed with prejudice.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Seventy-fifth Defense

75. Plaintiffs lack standing because Defendants did not engage in deceptive conduct with regard to Plaintiffs or otherwise.

Seventy-sixth Defense

76. In the event Plaintiffs recover a verdict or judgment against Defendants, then said verdict or judgment must be reduced pursuant to CPLR 4545(c), and/or other applicable State or Commonwealth statutes, by those amounts which have, or will, with reasonable certainty, replace or indemnify Plaintiffs, in whole or in part, for any past or future claimed medical expenses or other such economic loss, paid from any collateral source such as insurance, social security, workers' compensation or employee benefit programs.

Seventy-seventh Defense

77. In accordance with CPLR 1601 et seq., and/or other applicable State or Commonwealth statutes, the liability of Defendants, if any, to Plaintiffs for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to the total liability for non-economic loss, including named parties and others over whom Plaintiffs could have obtained personal jurisdiction with due diligence.

Seventy-eighth Defense

78. In accordance with General Obligations Law 15-108, if Plaintiffs execute a release or a covenant not to sue for a tortfeasor in this action, Plaintiffs' damage claim against Defendants is reduced to the extent of any amount stipulated by the release or covenant, or in the amount of consideration paid for it, or in the amount of the released tortfeasor's equitable share of the damages under CPLR 1401 et seq., whichever is greatest.

Seventy-ninth Defense

79. The conduct of Defendants and all activities with respect to the subject products were fair and truthful based upon the knowledge existing at the relevant time alleged in the Complaint. Therefore, Plaintiffs' claims under New York Business Corporation Law § 349 are barred.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Eightieth Defense

80. Plaintiffs' claims are barred by the limitations and defenses set out in the Missouri Product Liability Act, Mo. Rev. Stat. § 537. 760 *et seq.*, including but not limited to, the "state of the art" defenses as defined in Mo. Rev. Stat. § 537.764. Defendants incorporate by reference all defenses and/or limitations set forth or referenced in the Missouri Product Liability Act.

Eighty-first Defense

81. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants is not liable in any way. Mo. Rev. Stat. § 537.765.

Eighty-second Defense

82. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Missouri, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Eighty-third Defense

83. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Missouri law.

Eighty-fourth Defense

84. Defendants deny that they are liable for any damages in this case. Defendants contend, however, that any damage award to Plaintiffs that utilizes the Missouri joint and several liability scheme would be unconstitutional, as this scheme is violative of Defendants' due process and equal protection guarantees under the United States and Missouri Constitutions. The Missouri joint and several liability scheme, under Mo. Rev. Stat. § 537.067, violates

Defendants' due process guarantees because no legitimate state interest supports § 537.067, and, furthermore, no rational relationship exists between a legitimate state interest and the promotion of the Missouri joint and several liability scheme. Additionally, the Missouri system of assessing joint and several liability violates Defendants' equal protection guarantees because it operates to create arbitrary classifications of individuals, and to treat similarly situated individuals dissimilarly under the law. The joint and several liability scheme is also unconstitutionally void for vagueness under the United States and Missouri Constitutions. Thus, the scheme is unconstitutional and should not be applied in this action.

Eighty-fifth Defense

85. The imposition of punitive damages pursuant to current Alabama law violates the Due Process and Equal Protection provisions of the Fourteenth Amendment to the United States Constitution; to wit, Defendants have not been given fair notice of the standard of conduct which could subject them to a claim for punitive damages, and have not been given fair notice of the amount of punitive damages that may accompany a finding of liability. Alabama's current laws regarding punitive damages do not serve a rational or legitimate state interest.

Eighty-sixth Defense

86. Defendants plead the applicability of the Washington Products Liability Act, RCW 7.72 et seq., and specially aver that Plaintiffs' common law claims are preempted by the statute and must be dismissed.

Eighty-seventh Defense

87. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

- 1 3. That Defendants be awarded their costs for this lawsuit;
- 2 4. That the trier of fact determine what percentage of the combined fault or other liability
- 3 of all persons whose fault or other liability proximately caused Plaintiffs' alleged
- 4 injuries, losses or damages is attributable to each person;
- 5 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater
- 6 than an amount which equals their proportionate share, if any, of the total fault or other
- 7 liability which proximately caused Plaintiffs' injuries and damages; and
- 8 6. That Defendants have such other and further relief as the Court deems appropriate.
- 9

10 October 12, 2007

GORDON & REES LLP

11
12 By: : _____/s/
13 Stuart M. Gordon
14 sgordon@gordonrees.com
15 Embarcadero Center West
16 275 Battery Street, 20th Floor
17 San Francisco, CA 94111
18 Telephone: (415) 986-5900
19 Fax: (415) 986-8054

17 October 12, 2007

TUCKER ELLIS & WEST LLP

18
19 By: : _____/s/
20 Michael C. Zellers
21 michael.zellers@tuckerellis.com
22 515 South Flower Street, Suite 4200
23 Los Angeles, CA 90071
24 Telephone: (213) 430-3400
25 Fax: (213) 430-3409

26
27 Attorneys for Defendants
28 PFIZER INC, PHARMACIA
CORPORATION, and G.D. SEARLE
LLC

JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

_October 12, 2007

GORDON & REES LLP

By: : _____/s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

_October 12, 2007

TUCKER ELLIS & WEST LLP

By: _____/s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants
PFIZER INC, PHARMACIA
CORPORATION, and G.D. SEARLE
LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111